

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) and (a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. FDA did not receive any comments on this issue and, thus, is aware of no reason to alter this determination.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA did not receive any comments or new information on this issue, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1101 is amended by revising paragraphs (a) and (e) to read as follows:

§ 184.1101 Diacetyl tartaric acid esters of mono- and diglycerides.

* * * * *

(a) Diacetyl tartaric acid esters of mono- and diglycerides, also known as DATEM, are composed of mixed esters of glycerin in which one or more of the hydroxyl groups of glycerin has been esterified by diacetyl tartaric acid and by fatty acids. The ingredient is prepared by the reaction of diacetyl tartaric anhydride with mono- and diglycerides that are derived from edible sources.

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(e) *Labeling.* The acronym "DATEM" may be used on food labeling as the alternate common or usual name for the ingredient diacetyl tartaric acid esters of mono- and diglycerides.

Dated: March 17, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

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21 CFR Part 886

[Docket No. 94M-0260]

Medical Devices; Exemptions From Premarket Notification for Certain Classified Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of December 7, 1994 (59 FR 63005). The document exempted 148 generic types of class I devices from the requirement of premarket notification, with limitations. The document was published with an error in the codified section. This document corrects that error.

EFFECTIVE DATE: January 6, 1995.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4765, ext. 157.

In FR Doc. 94-30025, appearing on page 63005 in the **Federal Register** of Wednesday, December 7, 1994, the following correction is made:

§ 886.4350 [Corrected]

On page 63013, in the third column, in § 886.4350, paragraph (b) is corrected by removing the words "only when the device meets the ANSI standard on optic radiation limits."

Dated: March 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-7512 Filed 3-27-95; 8:45 am]

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DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 41

[Public Notice 2177]

VISAS: Passports and Visas Not Required for Certain Nonimmigrants

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule extends the Visa Waiver Pilot Program to September 30, 1996 and creates a new probationary status for certain countries which meet the requirements for that status under the Visa Waiver Pilot Program and which are designated by the Secretary of State and the Attorney General, acting jointly, as countries whose nationals benefit from the waiver of the nonimmigrant B-1/B-2 visa requirement. The extension of time for the Visa Waiver Pilot Program applies to those countries already in the program as well as to any countries which may be designated thereunder in the future. A statistical analysis was made to determine which countries could become visa waiver pilot countries with probationary status. As a result of that initial analysis it has been determined that Ireland, currently, is the only country which meets the criteria set forth for such countries.

DATES: This interim rule is effective on April 1, 1995. Written comments are invited and must be received on or before May 30, 1995.

ADDRESSES: Written comments may be submitted, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20522-0113.

FOR FURTHER INFORMATION CONTACT:

Stephen K. Fischel, Chief, Legislation and Regulations Division, Visa Office, Department of State, Washington, DC 20522-0113 (202) 663-1204.

SUPPLEMENTARY INFORMATION: This interim rule amends part 41, title 22 of the Code of Federal Regulations concerning visas for nonimmigrants pursuant to section 217 of the Immigration and Nationality Act (INA), 8 U.S.C. 1187, as amended by Pub. L. 103-415, 108 Stat. 4299, approved: 10/